Remarks

Claims 1-14, 16, 19-23, and 26 have been amended in order to write these claims in the appropriate U.S. claim format, to correct errors in spelling and syntax, and to eliminate multiple dependencies.

Claim 14, as amended, combines original claims 14 and 15, and amended claim 16 combines original claims 16 and 17. Alternative elements (i)-(iv) of original claim 13 are claimed separately in new claims 31-34. Otherwise, the new claims correspond to the original claims written in singly dependent form.

Claims 1-14, 16, 19-23, 26, 27, and 75 are in the application as amended.

Attached hereto is a marked-up version of the changes made to the specification and claims by the instant amendment. The marked-up version is entitled "Version With Markings To Show Changes Made".

Respectfully submitted,

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Version With Markings to Show Changes Made

In the Claims:

Claims 1-14 have been amended as follows:

1. (Amended) A pharmaceutical composition comprising a short acting hypnotic or a salt thereof [characterised in that it consists of a timed dual release dosage form] adapted to release the short acting hypnotic over a predetermined time period, according to an *in vitro* profile of dissolution [when measured in a rotating paddle apparatus of the European pharmacopoeia in aqueous buffer at 37°C], comprising two release pulses, the first being immediate and the second being delayed by a fixed time after the administration.

2. (Amended) A pharmaceutical composition according to claim 1, [characterised in that] wherein the first pulse has a maximum duration of 30 minutes.

3. (Amended) A pharmaceutical composition according to claim 1 [or 2, characterised in that] wherein the fixed time is between 50 and 200 minutes.

4. (Amended) A pharmaceutical composition according to claim 3[, characterised in that] wherein the fixed time is between 60 and 150 minutes.

5. (Amended) A pharmaceutical composition according to [any one of claims 1 to 4, characterised in that] claim 1 wherein 40 to 70% of the total amount of the short acting hypnotic is released during the immediate release pulse.

6. (Amended) A pharmaceutical composition according to [any one of claims 1 to 5, characterised in that] claim 1 wherein the delayed release pulse lasts between 30 and 200 minutes.

7. (Amended) A pharmaceutical composition according to [any one of claims 1 to 6, characterised in that] claim 1 wherein the time for release of 85% of the [toal] total amount of the short acting hypnotic is between 2 and 6 hours.

8. (Amended) A pharmaceutical composition [comprising] containing a short acting hypnotic or a salt thereof, according to [anyone of claims 1-7, characterised in that it comprises] claim 1 comprising two kinds of pharmaceutical entities: one immediate release entity and one delayed release entity.

9. (Amended) A pharmaceutical composition according to claim 8[, characterised in that it consists in] as a dosage form [chosen among] selected from the group consisting of capsules, tablets, multilayer tablets, multicoated tablets.

10. (Amended) A pharmaceutical composition according to claim 8 [or 9, characterised in that it consists of] as a capsule comprising one or more immediate release tablets and one or more delayed release tablets.

11. (Amended) A pharmaceutical composition according to claim 8 [or 9, characterised in that it consists of] as a capsule comprising a mixture of delayed release particles and immediate release particles.

12. (Amended) A pharmaceutical composition according to claim 8 [or 9, characterised in that it consists of] as a capsule comprising a mixture of delayed release particles and an immediate release powder.

13. (Amended) A pharmaceutical composition according to claim 8 [or 9, characterised in that it consists of] as a tablet comprising a number of delayed release coated pellets comprising the [drug] short-acting hypnotic imbedded in a matrix [and alternatively in that

(i) the matrix comprises the drug,

(ii) immediate release non-coated pellets are mixed to the delayed release coated pellets,

(iii) the delayed coated pellets are further coated with a layer comprising the drug, allowing immediate release form that layer, imbedded in a matrix free from the drug,

(iv) the tablet consists of one or more layers comprising the delayed release pellets imbedded in a matrix free from the drug and one or more layers containing the drug in an immediate release matrix].

14. (Amended) A pharmaceutical composition according to [any one of claims 10 to 13, characterised in that] claim 10 wherein the delayed release [particles or] tablets are coated with [a mixture containing] at least one ammonio [methacylate] methacrylate copolymer and the core contains a cationic or zwitterionic surfactant.

16. (Amended) A pharmaceutical composition according to claim 14[, characterised in that] wherein the cationic surfactant is [chosen among] selected from the group consisting of trimethyl-dimyristoyl-ammonium propionate, dimethyl-dioctadecyl-ammonium bromide, trimethyl-cetyl-ammonium bromide, dimethyl-didodecyl-ammonium bromide, benzalkonium chloride, cetylpyridinium chloride and cetrimide and the zwitterionic surfactant is selected from the group consisting of N-alylbetaines, C-alkylbetaines, N-alkylamidobetaines, N-alkylglycines, phosphatidylcholines and lecithins.

19. (Amended) A pharmaceutical composition according to claim 8[, characterised in that] wherein the immediate release entity and the prolonged release entity are administered simultaneously but separately.

20. (Amended) A pharmaceutical composition according to [anyone of claims 8 to 18, characterised in that the prolonged] claim 8 wherein the delayed release entity comprises a [pharmaceutical] pharmaceutically acceptable organic acid [which can be chosen among] selected from the group consisting of tartaric, malic, fumaric, lactic, citric, adipic or succinic acid and their [acid] salts, in the form of racemates or isomers.

21. (Amended) A pharmaceutical composition according to [any one of claims 1 to 20, characterised in that] claim 1 wherein the short acting hypnotic belongs to the therapeutic classes of benzodiazepines, cyclopyrrolones, pyrazolopyrimidines, [phenotiazines] phenothiazines or imidazopyridines.

22. (Amended) A pharmaceutical composition according to claim 21[, characterised in that] wherein the short acting hypnotic is chosen [among] from triazolam, temazepam, brotizolam, zolpiclone, (*R*)-zopiclone, zaleplon, alimemazine, zolpidem and [their] pharmaceutically acceptable salts thereof.

23. (Amended) A pharmaceutical composition according to claim [21, characterised in that] 22 wherein the short acting hypnotic is zolpidem or a pharmaceutically acceptable salt thereof.

26. (Amended) A pharmaceutical composition according to claim [25, characterised in that] 73 wherein the visual [means are chosen among inclusion of colouring excipients] change is chosen from a change in color, floating of the composition at the surface of the drink, and formation of insoluble particles on the surface of the drink, on the brim of the glass, in the drink and/or on the bottom of the glass or a combination thereof.

Claims 15, 17, 18, 24, and 25 have been cancelled.

Claims 27-75 have been added.